



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2014

Esaote S.p.A.
% Ms. Allison Scott
Senior Consultant
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
INDIANAPOLIS IN 46268

Re: K142008
Trade/Device Name: 6400 and 7400 Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 22, 2014
Received: July 23, 2014

Dear Ms. Scott:

This letter corrects our substantially equivalent letter of September 12, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the 6400 & 7400 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number- 6400

SP2430	SP2442	LA435
LA523	AL2442	AL2443
SL1543	SL2325	AC2541
SC3123	CA430	S2MCW
S5MCW	SHFCW	S2MPW
SE3123	EC1123	TRT33
ST2613	ST2612	IOT342

IOT332	IOE323	LP323
BC431	BC441	SB2C41
BE1123	SB3123	

Transducer Model Number- 7400

SP2430	SP2442	AL2442
AL2443	SL1543	SL2325
AC2541	SC3123	S2MCW
S5MCW	SHFCW	S2MPW
SE3123	EC1123	ST2613
ST2612	IOT342	SB2C41
SB3123		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142008

Device Name

MyLabAlpha (7400), MyLabSeven (6400)

Indications for Use (Describe)

Esaote's Model 6400 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal, Laparoscopic and Other: Urologic. The 6400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 7400 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal and Other: Urologic. The 7400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

6400

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TI _B)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P: 5, 6
Abdominal	P	P	P	P	P	P	P		P	P: 5, 6
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5
Adult Cephalic	P	P	P	P	P	P	P		P	P: 5
Cardiac [2]	P	P	P	P	P	P	P	P	P (7)	P: 5
Transesophageal (Cardiac) [2]	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6
Transvaginal	P	P	P		P	P	P		P	P: 5, 6
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5
Laparoscopic	N	N	N		N	N	N		N	N: 5
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P	P	P	P	P		P	P: 5

N: New Indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

[7] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k111302, K132231, K132466

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

7400

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P: 5, 6
Abdominal	P	P	P	P	P	P	P		P	P: 5, 6
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5
Adult Cephalic	P	P	P	P	P	P	P		P	P: 5
Cardiac [2]	P	P	P	P	P	P	P	P	P (7)	P: 5
Transesophageal (Cardiac) [2]	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, E: 6
Transvaginal	P	P	P		P	P	P		P	P: 5, E: 6
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P	P	P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D / 4D

[7] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and

Previously cleared via k111302, K132231, K132466

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SP2430 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P: 5
Abdominal	P	P	P	P	P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 5
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5
Adult Cephalic	P	P	P	P	P	P	P		P	P: 5
Cardiac [2]	P	P	P	P	P	P	P	P	P (7)	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[7] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k132466

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SP2442 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P: 5
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P: 5
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k132231

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

LA435 (6400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via K140677

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

LA523 (6400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via K140677

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

AL2442 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

AL2443 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k132466

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SL1543 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SL2325 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5
Small Organs [1]	E	E	E		E	E	E		E	E: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E: 5
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

To be cleared with this submission

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

AC2541 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)	P	P	P		P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SC3123 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	E	E	E		E	E	E		E	E: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E: 5
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	E	E	E		E	E	E		E	E: 5
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

CA430 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E: 5
Abdominal	E	E	E		E	E	E		E	E: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E: 5
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E: 5
Other (Urological)	E	E	E		E	E	E		E	E: 5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

S2MCW (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

S5MCW (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SHFCW (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

S2MPW (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic			P							
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

[5] Compound Imaging (Mview)

Previously cleared via k132466

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SE3123 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5
Transvaginal	P	P	P		P	P	P		P	P: 5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

EC1123 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5
Transvaginal	P	P	P		P	P	P		P	P: 5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via K140677

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

TRT33 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

ST2613 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	E	E	E	E	E	E	E	E	E	E; 5
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

To be cleared with this submission

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

ST2612 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P: 5
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

IOT342 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

IOT332 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

IOE323 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

		Mode of Operations								
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P: 5
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5
Small Organs [1]	P	P	P		P	P	P		P	P: 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via K140677

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

LP323 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	P: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic	P	P	P		P	P	P		P	P: 5
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

Previously cleared via K140677

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

BC431 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6
Abdominal	P	P	P		P	P	P		P	P: 5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

BC441 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6
Abdominal	P	P	P		P	P	P		P	P: 5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SB2C41 (6400 AND 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

		Mode of Operations								
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6
Abdominal	P	P	P		P	P	P		P	P: 5, 6
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

Previously cleared via k141486

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

BE1123 (6400 system)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

		Mode of Operations								
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5, 6
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5, 6
Transvaginal	P	P	P		P	P	P		P	P: 5, 6
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

Previously cleared via k133905

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

SB3123 (6400 and 7400 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E: 5, 6
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	E	E	E		E	E	E		E	E: 5, 6
Transvaginal	E	E	E		E	E	E		E	E: 5, 6
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D

Previously cleared via k132231

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH

Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

Submitter Information

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Date: July 22, 2014

807.92(a)(2)

Devices

Common Name: Ultrasound Imaging System

Trade Name: 6400 Ultrasound System
7400 Ultrasound System

Classification Name(s): Ultrasound Pulse Doppler Imaging System 892.1550
Ultrasound Pulse Echo Imaging System 892.1560
Transducer, Ultrasonic, Diagnostic 892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

Predicate Device(s)

Device	Owner	510(k)
6400 7400	Esaote	K111302, K132231, K132466
7340	Esaote	K081794, K091009, K110688

Device	Owner	510(k)
6150	Esaote	K051308, K052805, K060827, K081386, K091009

807.92(a)(4)

Device Description

Model 6400 is a mainframe system equipped with wheels allowing to move the system. Model 7400 is a portable system equipped with a handle. The system size and weight allow it to be carried using its handle. The primary modes of operation are for both models: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), Doppler, Color Flow Mapping (CFM), Amplitude Doppler (AD), Tissue Velocity Mapping (TVM), 3D and 4D. Both 6400 and 7400 are equipped with a LCD color display where acquired images and advanced image features are shown. Both 6400 and 7400 can drive Phased, Convex, Linear array, Doppler probes and Volumetric probes (Bi-Scan probes). 6400 control panel is equipped with a pull-out Qwerty alphanumeric keyboard that allows data entry. On 7400 model the touchscreen has an emulation of the Qwerty alphanumeric keyboard that allows data entry. Both 6400 and 7400 models are equipped with wireless capability. Model 7400 has been designed to be powered by battery.

Both 6400 and 7400 have been cleared via k111302, K132231 and K132466.

6400 and 7400 Upgrades, defined herein, combine the cleared features of both 6400 and 7400 systems with new capabilities, listed below:

1. Management of Quality Intima Media Thickness (QIMT) on both 6400 and 7400 upgrades.
2. Management of Elastosonography qualitative analysis (ElaXto) on both 6400 and 7400 upgrades.
3. Management of Laparoscopic application on 6400 upgrade.

The 6400 and 7400 Upgrades are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use

Esaote's Model 6400 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal, Laparoscopic and Other: Urologic. The 6400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 7400 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal and Other: Urologic. The 7400 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

The 6400 and 7400 Upgrades employ the same fundamental technological characteristics as their predicate devices.

The 6400 Upgrade model is substantially equivalent to Esaote 6150 model cleared via K051308, K052805, K060827, K081386, K091009 and to Esaote 6400 model cleared by FDA via K111032, K132231, K132466.

The 7400 Upgrade model is substantially equivalent to Esaote 7340 model cleared via K081794, K091009, K110688 and to Esaote 7400 model cleared by FDA via K111032, K132231, K132466.

- Clinical uses for which Esaote 6400 and 7400 models have been cleared by FDA via K111032, K132231, K132466 are not changed by 6400 and 7400 Upgrades, to be cleared via this submission.
- Clinical uses for which Esaote 6400 and 7400 Upgrades are designed are equivalent to those of Esaote 6150 model, cleared via K051308, K052805, K060827, K081386, K091009, and of Esaote 7340 model, cleared via K081794, K091009, K110688.
- 6400 Upgrade and 7400 upgrade for managing Quality Intima Media Thickness (QIMT) are equivalent to those of Esaote 6150 model, cleared via cleared via K051308, K052805, K060827, K081386, K091009, and of Esaote 7340 model, cleared via K081794, K091009, K110688.
- 6400 Upgrade and 7400 Upgrade for managing Elastasonography qualitative analysis are equivalent to those of Esaote 6150 model, cleared via cleared via K051308, K052805, K060827, K081386, K091009, and of Esaote 7340 model, cleared via K081794, K091009, K110688.
- 6400 Upgrade for managing Laparoscopic application is equivalent to those of Esaote 6150 model, cleared via K051308, K052805, K060827, K081386, K091009.
- Esaote 6400 Upgrade, 7400 Upgrade, 6400, 7400, 6150 and 7340 are designed to meet the IEC60601-1.
- Esaote 6400 Upgrade, 7400 Upgrade, 6400, 7400, 6150 and 7340 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 6400 Upgrade, 7400 Upgrade, 6400, 7400, 6150 and 7340 ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

Summary of Non-Clinical Tests

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-2-37
- NEMA UD-3 - Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The 6400 and 7400 Upgrades are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.